

§ 524.1484e

equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. Instill a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily.

(2) *Indications for use*. For the treatment of ear canker and other inflammatory conditions of the external ear canal, acute otitis externa and, to a lesser degree, chronic otitis externa.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984; 79 FR 10970, Feb. 27, 2014]

§ 524.1484e Neomycin and polymyxin B ophthalmic solution.

(a) *Specifications*. Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1 to 2 drops per eye every 6 hours.

(2) *Indications for use*. For the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10970, Feb. 27, 2014]

§ 524.1484f Neomycin, prednisolone, and tetracaine otic suspension.

(a) *Specifications*. The product contains 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

21 CFR Ch. I (4–1–14 Edition)

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. Instill 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use*. For the treatment of acute otitis externa and, to a lesser degree, chronic otitis externa; as treatment or adjunctive therapy of certain ear conditions caused by or associated with neomycin-susceptible organisms and/or allergy.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.

(a) *Specifications*. Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*. In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (2 to 4 drops per square inch) twice daily. In treating otitis externa, instill 5 to 15 drops in the ear twice daily. Treat for up to 7 days.

(2) *Indications for use*. As an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 10971, Feb. 27, 2014]

§ 524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.

(a) *Specifications*. Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin